

§ 184.1240

and 0.07 percent or less for all other food categories.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[45 FR 6086, Jan. 25, 1980; 45 FR 26319, Apr. 18, 1980, as amended at 49 FR 5611, Feb. 14, 1984]

§ 184.1240 Carbon dioxide.

(a) Carbon dioxide (empirical formula CO₂, CAS Reg. No. 124-38-9) occurs as a colorless, odorless, noncombustible gas at normal temperatures and pressures. The solid form, dry ice, sublimates under atmospheric pressure at a temperature of -78.5 °C. Carbon dioxide is prepared as a byproduct of the manufacture of lime during the "burning" of limestone, from the combustion of carbonaceous material, from fermentation processes, and from gases found in certain natural springs and wells.

(b) The Food and Drug Administration is developing food-grade specifications for carbon dioxide in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a leavening agent as defined in §170.3(o)(17) of this chapter; a processing aid as defined in §170.3(o)(24) of this chapter; and a propellant, aerating agent, and gas as defined in §170.3(o)(25) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 57270, Dec. 29, 1983]

§ 184.1245 Beta-carotene.

(a) *Beta*-carotene (CAS Reg. No. 7235-40-7) has the molecular formula C₄₀H₅₆.

21 CFR Ch. I (4-1-02 Edition)

It is synthesized by saponification of vitamin A acetate. The resulting alcohol is either reacted to form vitamin A Wittig reagent or oxidized to vitamin A aldehyde. Vitamin A Wittig reagent and vitamin A aldehyde are reacted together to form *beta*-carotene.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 73, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: dairy product analogs as defined in §170.3(n)(10) of this chapter; fats and oils as defined in §170.3(n)(12) of this chapter; and processed fruits and fruit juices as defined in §170.3(n)(35) of this chapter. *Beta*-carotene may be used in infant formula as a source of vitamin A in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act or with regulations promulgated under section 412(g) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[52 FR 25211, July 6, 1987]

§ 184.1250 Cellulase enzyme preparation derived from *Trichoderma longibrachiatum*.

(a) Cellulase enzyme preparation is derived from a nonpathogenic, nontoxicogenic strain of *Trichoderma longibrachiatum* (formerly *T. reesei*). The enzyme, cellulase, catalyzes the endohydrolysis of 1,4-beta-glycosidic linkages in cellulose. It is obtained